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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,420	11/29/2004	Anders Magnusson	ASZD-P01-707	3009
28120	7590	03/06/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			SILVERMAN, ERIC E	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/516,420	Applicant(s) MAGNUSSON ET AL.	
	Examiner Eric E. Silverman, PhD	Art Unit 1615	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 3-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: ____.  | 6) <input checked="" type="checkbox"/> Other: <u>NPL</u> .                  |

### **DETAILED ACTION**

Examiner notes that no information disclosure statement is of record in association with this application. Receipt of the certified translation of Swedish priority documents, filed 11-29-2004, is acknowledged. Claims 1 – 13 are pending in this action.

#### ***Claim Objections***

Claims 3 - 11 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot be dependant on another multiply dependant claim. See MPEP § 608.01(n).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to claim 1, it is unclear how the formulation can contain "only iota-carrageenan and a neutral gelling polymer" if the pharmaceutical compound recited in the claim must also be in the compound. For the purposes of expedient examination, Examiner will presume that Applicant intended to mean that iota-carrageenan and a neutral gelling polymer are the only permissible ingredients other than the active agent.

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Clarification is requested. The remaining claims, 2 – 13, are rejected at least in part for depending on claim 1.

With regard to claim 13, it is unclear how the purpose of the method, namely treating a cardiovascular disorder, can be achieved in a patient who does not have such a disorder, but is merely 'at risk of' said disorder, as recited in part by instant claim.

Clarification is requested.

With regard to claim 10, it is unclear how a composition that contains "only iota-carrageenan and a neutral gelling polymer when the compound is a salt", as recited in independent claim 1, may also contain SDS, which is neither iota-carrageenan nor a neutral gelling polymer, but an ionic surfactant. Claim 10 is therefore so confusing as to be unsearchable, accordingly no search is being conducted for this claim. Clarification is requested.

Claims 11 and 12 provide for the use of a composition, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11 and 12 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an

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improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### **Conclusion**

No Claims are allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 98/016252, CAS RN 303184-53-4, CAS RN 192939-72-3 CAS RN 759776-70-2, and Bonferoni et al., Journal of Controlled Release (1994) Vol 30 pp 175 – 182.

The WO document teaches other thrombin inhibitors in gelling matrices alike to those in instant claims, the structures of the inhibitors being taught in the CAS documents. These inhibitors are structurally related to the ones of instant claims, but have one different chemical moiety. There is no suggestion in the prior art of record to change said moiety in such a manner as to arrive at the compounds of instant claims.

Bonferoni teaches a controlled release matrix for drugs which consists of carrageen and hydroxypropylmethylcellulose.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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